

In re Application of:

Applicant: Robertson et al.

Serial No.: 09/382,242

Filed: August 24, 1999

Title: ESTERASES

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## REMARKS

Claims 21-26 were pending before this Response. By the present communication, the Specification is amended at pages 2 and 5 to delete a single paragraph pertaining to ATCC deposit that contains a blank. In addition, claims 21 and 26 are amended to define Applicants' invention with greater particularity and to focus the invention on the elected species. The amendments add no new matter, the amended language being fully supported by the original specification and claims. Applicant submits that the claim amendments do not narrow the claims in any way within the meaning of Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., a/k/a SMC Corporation and SMC Pneumatics, Inc. 234 F.3d 558, 51 U.S.P.Q. 2d 1959 (Fed. Cir. 2000). Accordingly, claims 21-26 are currently pending.

### The Objection to the Specification

The specification is objected to as informal for containing blanks on pages 2 and 5 and appropriate correction is requested. Accordingly, Applicants have amended the Specification at pages 2 and 5 to delete a single paragraph pertaining to ATCC deposit that contains a blank. In view of these amendments to the Specification, Applicants respectfully request reconsideration and withdrawal of the objection to the Specification for informalities.

### The Double Patenting Rejection

Applicants traverse the rejection of claims 21-26 under the judicially created doctrine of obviousness-type double patenting over claims 1-6 of U. S. Patent No. 5,942,430. Applicants submit herewith a Terminal Disclaimer disclaiming the terminal part of part of any patent granted on the above-identified Application No. 09/382,242 that would extend beyond the expiration date of U.S. Patent No. 5,942,430. In addition, Applicants submit that Diversa Corporation owned both the subject matter of the present application and that of U.S. Patent No.

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5,942,430 at the filing date of the present application. In view of the Terminal Disclaimer, Applicants respectfully submit that U.S. Patent No. 5,942,430 is not available as prior art against the present application under the judicially created doctrine of obviousness-type double patenting. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

### **The Rejection Under 35 U.S.C. §112, Second Paragraph**

Applicants respectfully traverse the rejection of claims 21-26 under 35 U.S.C. §112, Second Paragraph as allegedly being indefinite. The Examiner asserts that claim 26 is confusing as it appears to be broader than claim 24 from which it depends. To overcome this appearance of indefiniteness, by the present communication, claim 26 has been rewritten in independent claim format.

In addition, the Examiner asserts that the term "hybridizes" renders claim 26 indefinite absent a statement of the conditions under which the hybridization reaction is performed (Office Action, page 4). By the present communication, claim 26 has also been amended to require that hybridization of the invention catalase probes occurs "under conditions of medium to reduced stringency". The Specification provides guidelines regarding stringency conditions (Specification, page 9, line 22 to page 10, line 6). In addition, Applicants respectfully submit that those of skill in the art could use the guidelines provided in the Specification to determine alternative conditions for hybridization that would be considered by those of skill in the art as being of equivalent reduced to medium stringency, depending upon the exact length of the nucleic acid sequence being utilized as a probe.

In view of the amendments to claim 26, Applicants respectfully submit that amended claim 26 meets all requirements under 35 U.S.C. § 112, Second Paragraph.

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### **The Rejection Under 35 U.S.C. § 102(a or b)**

Applicant respectfully traverses the rejection of claims 21, 22, and 26 as allegedly being anticipated by GenBank Accession No. X864787 or Kim et al. (*The Journal of Biological Chemistry* (1992) **267** (11):7710-7717). Applicant respectfully submits that the invention nucleic acid probe, as defined by amended claim 21 distinguishes over both GenBank X864787 and Kim et al. by "consisting of" about 15 to 50 contiguous nucleotides of a polynucleotide having a sequence as set forth in SEQ ID NO:23. The GenBank sequence contains 385 nucleotides, of which the allegedly anticipatory region is only bases 21-39, and GenBank X864787 contains no teaching to select these particular 15 to 50 contiguous nucleotides from the 385 nucleotides for a probe molecule.

Similarly the gene disclosed by Kim et al. contains more than 5069 nucleotides, of which the allegedly anticipatory region is only bases 4051-5069, and Kim et al. contains no teaching to select these particular 15 to 50 contiguous nucleotides from the more than 5069 nucleotides for a probe molecule.

Applicants further respectfully submit that the invention oligonucleotide probe, as defined by amended claim 26, distinguishes over the disclosure of each of GenBank X864787 and Kim et al. by "comprising a sequence which specifically hybridizes under medium to reduced stringency conditions to a nucleic acid comprising SEQ ID NO:23 or a sequence fully complementary thereto to form a detectable target probe duplex." GenBank X864787 discloses a *Clostridium perfringens* dhaT gene, but fails to disclose selection of a sequence thereof that specifically hybridizes to a nucleic acid comprising SEQ ID NO:23, which encodes an esterase, to form a detectable target probe duplex (i.e., having utility has a probe to identify an esterase). Similarly, Kim et al. discloses a sequence encoding the human transglutaminase 1 Gene, but fails to disclose selection of a sequence thereof that specifically hybridizes to a nucleic acid comprising SEQ ID NO:23, which encodes an esterase, to form a detectable target probe duplex (i.e., having utility has a probe to identify an esterase).

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Therefore, Applicants respectfully submit that neither GenBank X864787 nor Kim et al. provides each and every element of claim 21 or claim 26, as would be required to support a rejection for anticipation under 35 U.S.C. § 102. Accordingly, reconsideration and withdrawal of the rejection of claims 21, 22 and 26 as allegedly being anticipated under 35 U.S.C. § 102 (a or b) are respectfully requested.

In view of the above amendments and remarks, reconsideration and favorable action on claims 21-26 are respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call Applicant's representative at (858) 677-1456 so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date:

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## **EXHIBIT A**

### **A marked-up version of the amendments**

#### **In the Specification**

Please amend the Specification at pages 2, by deleting the paragraph beginning at line 11 as follows:

[In accordance with another aspect of the present invention there are provided isolated nucleic acid molecules encoding mature polypeptides expressed by the DNA contained in ATCC Deposit No. \_\_\_\_\_.]

Please amend the Specification at page 5, by deleting the paragraph beginning at line 16 as follows:

[In accordance with another aspect of the present invention, there are provided isolated polynucleotides encoding the enzymes of the present invention. The deposited material is a mixture of genomic clones comprising DNA encoding an enzyme of the present invention. Each genomic clone comprising the respective DNA has been inserted into a pBluescript vector (Stratagene, La Jolla, CA). The deposit has been deposited with the American Type Culture Collection, 12301 Parklawn Drive, Rockville, Maryland 20852, USA, on December 13, 1995 and assigned ATCC Deposit No. \_\_\_\_\_.]

#### **In the claims**

Please amend claims 21 and 26 as follows:

21. (Amended) An oligonucleotide probe consisting of [at least] about 15 to 50 contiguous nucleotides of a polynucleotide [selected from the group consisting of having a sequence as set forth in SEQ ID NO:23 [-31 and SEQ ID NO:32].

26. (Amended) An oligonucleotide probe comprising a sequence which specifically hybridizes under reduced to medium stringency conditions to a nucleic acid comprising SEQ ID NO:23 or a sequence fully complementary thereto to form a detectable target probe duplex.